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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/322,732	05/28/1999	KEITH R. MAROTTI	PUJ-0041	8413

34135 7590 03/11/2003

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EXAMINER	
ROBINSON, HOPE A	
ART UNIT	**PAPER NUMBER**
1653	28

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/322,732	Applicant(s) Marotti et al.
	Examiner HOPE ROBINSON	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 3, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8, 15-18, and 140-150* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8, 15-18, and 140-150* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to the Office Action mailed July 02, 2002, in Paper No. 25 on January 3, 2003 is acknowledged.

2. Claims 4, 5, 142 and 143 have been amended. Claims 4-8, 15-18 and 140-150 are pending.

3. The following grounds of rejection are or remain applicable :

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 15-18 and 140-150 remain rejected under 35 U.S.C. 112 first paragraph, because the specification is not enabled for the full scope of the claims, for example a method for identifying a compound (unspecified) that increases the activity of efp by contacting efp with a compound (unspecified). The specification is enabled for a binding assay using radio-labeled

oxazolidinone bound to efp (such as linezolid or eperezolid) see pages 15+ of the specification. However, the specification is not enabled for a method with an unspecified amount of compounds or a method to identify compounds that increase the activity of efp *per se* as the specification does not exemplify such a method. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in the art, predictability or unpredictability of the art and breadth of the claims, these factors are addressed below.

The claimed invention is directed to a method which encompasses any and all possible compounds and a method step that utilizes the unidentified compound in the process and a method that does not identify the specific efp activity that is increased. Note that the claimed method appears to be a binding assay although not disclosed as such. However, the specification provides only examples and no specific assays to accompany the claimed method. Furthermore, there is no indicia of how the claimed method is an improvement over the prior art. See for example on page 14 where the specification states that cell-free extract is an example of an assay that can be performed. In addition, the specification asserts that contacting can take place in buffers or media well known to those skilled in the art. Further, varying amounts of the test compound can be used as desired by the practitioner. Therefore, it appears that much of the

parameters involved in the method can be adjusted arbitrarily which invites one skilled in the art to perform undue experimentation.

Additionally, the specification asserts that the claimed method will identify a compound that modulates the activity of prokaryotic efp, determine whether the compound modifies activity of efp, for example determining if the compound binds to efp by a number of art-recognized procedures (i.e. binding assays such as gel-shift mobility electrophoresis, Western blot, filter binding and scintillation proximity assay). Note that the claimed method is relying on art-recognized procedures, yet the specification asserts that this is a new method/procedure. Furthermore, the information provided in the specification is exemplary and not limiting, therefore, does not breathe life into the claims. In view of the foregoing, one skilled in the art would have to engage in undue experimentation to be able to practice the full scope of the claims since the specification does not provide sufficient detail. In the absence of sufficient guidance/direction regarding the steps to determine whether the test compound modulates the activity of efp one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims. Further, the claimed methods do not have endpoints/results that correspond to the preamble of the claims, thus, it doesn't appear that objective of the method is obtained. In fact the claims read on a binding assay rather than a method to identify an compound that has the desired effect on efp. In addition, the claims broadly recite a method of identifying a compound that modulates the activity of efp, however, there is no specific assay and measurements to obtain this information nor information as to

whether modulation is up or down (see for example claim 141). Note for example that the prior art teaches that genes encoding certain ribosomal proteins can be deleted from the chromosome without an apparent effect on cell viability. It is also stated that most initiation, elongation and termination factors are required for cellular growth, however, some of these proteins may be dispensable under certain growth conditions (Aoki et al., The Journal of Biological Chemistry, vol. 272, no. 51, 1997). In view of the prior art the specification needs to provide guidance as to how the compound is determined, what the compound is, how the efp activity will be modulated, what effect the modulation will have on the function of the efp and a specific assay and measurement steps to achieve all of the above.

Absent exemplification of a specific assay to assay a specific compound the specification is not enabled for a method that modulates the activity of efp. Further, since no guidance or direction is provided regarding the determination of the test compound it would require undue experimentation to be able to practice the claimed invention.

Thus, for all of the above reasons, the specification is not considered to be enabling without undue experimentation, because, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to enable one skilled in the art to be able to practice the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4-8, 15-18 and 140-150 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the claim recites "a method for identifying a compound that increases the activity of prokaryotic elongation factor p" and it is unclear what activity of efp is being increased. The claim is further indefinite as there is no end result that indicates a specific compound has been identified, the method merely determines if binding occurred, which is not the objective of the method as recited in the permeable. With regard to the "determining" step, no measurement steps are included in the method. See also the dependent claims and independent claims that recite the above language (for example claim 5-8, 15-18 and 140-150).

Claim 6 is indefinite because the claim recites the phrase "determining whether said compound which increases the activity of efp increases the activity of other protein(s) essential for the functioning of efp" and it is unclear what the other proteins are and what activities of the other proteins are affected by the unspecified compound.

Claim 7 is indefinite because the claim is missing a transitional phrase, the claim should be amended as follows, "increases the activity of a L16 protein" (see also claims 140, 141, 145).

Claims 140 and 141 are indefinite because the claims recite a method that modulates the activity of L16 protein. However, the claim does not recite whether modulation will be upward

or downward. The claim is also indefinite as to the recitation of the L16 protein being in "association" with efp. What is this association?

6. Applicant's arguments filed on January 3, 2003 in Paper No. 26 has been fully considered however, the rejections under 35 U.S.C. 112, first and second paragraph remains. Regarding the rejection under 35 U.S.C. 112, second paragraph the response states that the term compound and activity are defined in the specification. However, the definition provided for activity does not breathe life into the claim as it does not specifically say what activity of the efp will be modified. For example on page 2 of the specification it is disclosed that efp stimulates efficiency of the peptidyltransferase activity of procaryotic ribosomes and modulates the efficiency of protein synthesis. Neither the claim or the specification indicates what specific activity the compound is going to alter, will it increase the protein synthesis activity of efp? Are all efp activity increased? Page 4 of the response states that measurement steps are not required to understand the scope of the claim. However, this statement is not correct as the claims are directed to a method that requires measurements. Furthermore, the method does not have the end point stated in the preamble. The method as claimed merely determines if binding occurred.

The response states that the specification indicates that one of the proteins that affect the activity of efp is L16 which means that the compound can also affect it. However, the limitations of the specification cannot be read into the claims. Further, the claim 6 recites "determining whether said compound which increases the activity of efp increases the activity of

other proteins essential for the functioning of efp" and the claim does not recite what activity of for example the L16 will be affected. Page 6 of the response states that adding a transitional phrase to claim 7 and other claims with this language would not make the claims more clear or definite. This statement is incorrect because the claims presently recite "determining whether said compound that increases the activity of efp increases the activity of L16 protein", there needs to be a transitional phrase to make proper sentence structure, for example, "determining whether said compound that increases the activity of efp increases the activity **of a L16 protein**". At page 6 of the response applicant contends that the term "modulate" is definite. However, the claim as written is ambiguous because the claim can be read with two different meanings which are opposing activity (i.e. increase/decrease). Applicant needs to recite one term in the claim and the word modulate needs to be deleted. It is noted that applicant has already amended claims to recite either increase or decrease separately some of the claims. Applicant contends the specification teach an association such as binding. The word association implies a relationship with something else but does not define what that relationship is, thus if applicant intend for the association recited to be binding then this term should be recited in the claim. As the arguments presented are not persuasive the rejections remain.

With regard to the rejection under 35 U.S.C. 112, first paragraph applicant's arguments were not found to be persuasive. The rejection remains because the claims are not enabled for the full scope. Presently the scope of the claim is a binding assay, however, the claims are directed to a method of identifying a compound that increases the activity of efp. The method is

absent an end point to indicate that in fact a compound was identified, and not just that binding occurred. The response states that a compound means any identifiable chemical or molecule, however, the issue raised is not the definition of a compound but what specific compounds will the method use as the specification is not enabled for an unspecified amount of compounds. The arguments presented on page 8 of the response have been addressed in the discussion of the rejection under 35 U.S.C. 112, second paragraph. On page 9 of the response applicant state that the specification provide broad general teachings of assays and examples of the claimed invention. The examples provided do not demonstrate a method of identifying a compound that increases the activity of efp, the examples exemplify an assay to identify a compound that binds efp.

The response alleges that undue experimentation is not required (see pages 10-11 of the response), however, the method as claimed is an invitation for one skilled in the art to engage in further experimentation for the reasons stated above. The Courts stated in *In re Gardner (166 USPQ 138)* that: the law requires that disclosure in an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. The situation at hand is analogous to that in *Genetech v. Novo Nordisk A/S 42 USPQ2d 1001.* As set forth in the decision of the Court: "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (FED. Cir. 1993)*; see also *Amgen Inc. v. Chugai Pharms. Co., 927 F.2d 1200, 1212, 18 USPQ2d 1016 (Fed*

Cir. 1991); In re Fisher, 427 F.2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').

"Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)* (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.'). Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. "It is true...that a specification need not disclose what is well known in the art. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed Cir. 1986).* However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the

novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research (emphasis added). Thus, the rejection remains.

Conclusion

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday and Wednesday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Christopher S. F. Low

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